K040843

APR 3 0 2004

Section 3
HemosIL von Willebrand Factor Activity
510(k) Summary (Summary of Safety and Effectiveness)

Submitted by:

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Summary Prepared:

March 31, 2004

Name of the Device:

HemosIL von Willebrand Factor Activity

Regulatory Information:

Regulation Section:	Factor Deficiency Test (864.7290)
Classification:	Class II
Product Code:	GGP
Panel:	Hematology

Identification of predicate device(s):

K000398 Shield Von Willebrand Factor Activity ELISA

Description of the device/intended use(s):

HemosIL von Willebrand Factor Activity is an automated latex enhanced immunoassay intended for the *in vitro* diagnostic quantitative determination of von Willebrand Factor Activity (VWF Activity) in human citrated plasma on IL Coagulation Systems.

The VWF Activity kit is a latex particle enhanced immunoturbidimetric assay to quantify VWF Activity in plasma. The activity of VWF is determined by measuring the increase of turbidity produced by the agglutination of the latex reagent. A specific anti-VWF monoclonal antibody adsorbed onto the latex reagent, directed against the platelet binding site of VWF (Glycoprotein Ib receptor), reacts with the VWF of patient plasma. The degree of agglutination is directly proportional to the activity of VWF in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

HemosIL von Willebrand Factor Activity is substantially equivalent to the commercially available predicate device (Shield Von Willebrand Factor Activity ELISA) in performance and intended use.

Section 3 (Cont.)
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Summary of Performance Data:

Method Comparison

In separate method comparison studies on an ACL 9000 (n=108) using citrated plasma samples ranging from 0 to 192% VWF activity, the correlation statistics for HemosIL von Willebrand Factor Activity versus the predicate device are shown below:

	%VWF Activity		
IL System	**Slope**	**Intercept**	**r**
ACL 9000	0.832	4.782	0.972

Precision

Within run and total precision assessed over multiple runs using both three levels of control plasma gave the following results:

ACL 9000:	**Mean (% VWF Activity)**	**CV% (Within run)**	**CV% (Total)**
Normal Control	79.6	2.7	4.9
Special Test Controls Level 1	49.8	4.6	9.0
Special Test Controls Level 2	27.7	7.5	8.7

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 3 0 2004

Ms. Carol Marble
Director, Regulatory Affairs
Instrumentation Labortory Co.
113 Hartwell Avenue
Lexington, MA 02421

Re: k040843
Trade/Device Name: HemosIL von Willebrand Factor Activity
Regulation Name: Factor deficiency test
Regulation Number: 21 CFR 864.7290
Regulatory Class: Class II
Product Code: GGP
Dated: March 31, 2004
Received: April 1, 2004

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Joseph L. Hackett

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K040843

Device Name: HemosIL von Willebrand Factor Activity

Indications for Use:

HemosIL von Willebrand Factor Activity is an *in vitro* diagnostic automated latex enhanced immunoassay intended for the quantitative determination of von Willebrand Factor Activity (VWF Activity) in human citrated plasma on IL Coagulation Systems by immunoturbidity.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040843

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.019)